**Contents**





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**Change history**

| Version | Valid and binding as of | Description, comments (by author) | Author's initials |
|---|---|---|---|
| **2.0** | **08.05.19** | **Declaration requirements modified for homeopathics and anthroposophics in the following sections.**<br>**Section 6.6.1: General requirements**<br>**Section 6.6.3: Declaration** | **lap** |
| 1.1 | 01.01.19 | 5.4: Formal modification: Reference Art. 61 and Art. 65 TPO | lap |
| **1.0** | **01.01.19** | **Implementation of TPO4** | **lap** |

# 1 Definitions, terms, abbreviations

## 1.1 Definitions and terms

Refer to Art. 4 TPA and Art. KPTPO for the definitions of terms relating to complementary medicines.

## 1.2 Abbreviations

| | |
|---|---|
| Ann. | Annex |
| Art. | Article |
| CD-ROM | Compact Disc Read-Only Memory |
| chap. | chapter |
| FeeO-Swissmedic | Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018 (SR 812.214.5) |
| GMP | Good Manufacturing Practice |
| HAB | Deutsches homöopathisches Arzneibuch [German Homeopathic Pharmacopoeia] |
| HAS List | List of homeopathic and anthroposophic substances (Ann. 6 KPTPO) |
| HOMANT | Notification procedure for homeopathic and anthroposophic medicinal products with no indication (electronic software) |
| KPTPO | Ordinance of 7 September 2018 of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Complementary and Phytotherapeutic Products |



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| | |
|---|---|
| | (Complementary and Phytotherapeutic Products Ordinance, KPTPO; SR 812.212.24) |
| Let. | letter |
| NarcCO | Ordinance of 25 May 2011 on Narcotics Control (SR 812.121.1) |
| No. | number |
| Para. | paragraph |
| Ph. Eur. | Pharmacopoeia Europaea |
| Ph.F. | Pharmacopée Française [French Pharmacopoeia] |
| SC List | List of Schüssler salts (Ann. 7 KPTPO) |
| TPA | Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21) |
| TPLRO | Ordinance of the Swiss Agency for Therapeutic Products of 9. November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22) |
| TPO | Ordinance of 21. September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO) (SR 812.212.21) |
| TSE | Transmissible Spongiform Encephalopathy |

# 2 Introduction and purpose

Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy with no indication may be authorised on the basis of a notification procedure provided the (active) substances are on a list (Art. 15 para. 1 let. a TPA). The HOMANT electronic software is available for notification purposes.
This guidance document describes the process and the requirements for the authorisation by the notification procedure of homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy with no indication. Since this guidance document is aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the guidance document is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.
The guidance document additionally refers to procedures following authorisation.

# 3 Scope

The guidance document applies to the authorisation by the notification procedure of homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy with no indication, in accordance with Art. 27 KPTPO and for Schüssler salts in accordance with Art. 28 KPTPO.

It therefore does not apply to categories of medicinal products that are regulated in one of the following guidance documents:

- Guidance document *Authorisation of Homeopathics, anthroposophics and other complementary medicinal products HMV4* (for complementary medicines that do not fulfil the criteria for the notification procedure)
- Guidance document *Authorisation of Asian medicinal products HMV4*
- Guidance document *Authorisation of individual teas, cough and throat lozenges and pastilles in the notification procedure HMV4*

The stipulations in this guidance document in conjunction with the corresponding chapter of the stated documents must be observed for the procedures following authorisation described in this guidance document (application for variation, application for renewal of authorisation, notification of no marketing / interruption of distribution, notification of discontinuation).



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# 4 Legal framework

## 4.1 Authorisation

The notification procedure for the authorisation of homeopathic and anthroposophic medicinal products with no indication and of medicinal products for gemmotherapy with no indication are based in particular on the following legislation:

**TPA**

- Art. 4 Definition of terms
- Art. 10 Conditions for granting a marketing authorisation
- Art. 11 Application for a marketing authorisation
- Art. 15 Authorisation on the basis of a notification
- Art. 16 Duration of authorisation

**TPLRO**

- Art. 2 General preconditions
- Art. 12 Information and texts on containers and packaging materials
- Ann. 1a Information and texts on containers and packaging materials for homeopathic and anthroposophic medicinal products with no indication and medicinal products for gemmotherapy with no indication
- Ann. 3 Requirements for the declaration of active substances and pharmaceutical excipients in human medicinal products
- Ann. 3a List of excipients of particular interest

**NarcCO**

- Art. 4 para. 1 let. a Exceptions from the scope and from individual provisions

**KPTPO**

- Art. 4 Definition of terms
- Art. 5 Principle of simplified authorisation
- Art. 15 HAS List and SC List
- Chap. 4 no. 6 Authorisation on the basis of a notification for homeopathic and anthroposophic medicinal products with no indication and medicinal products for gemmotherapy with no indication
- Chap. 7 Authorisation on the basis of a notification (notification procedure), named product
  - Art. 37 Content
  - Art. 38 Basic company dossier
  - Art. 39 Master dossier for homeopathic and anthroposophic medicinal products
  - Art. 41 Single notifications
  - Art. 44 Labelling and medicinal product information for homeopathic and anthroposophic medicinal products with no indication and medicinal products for gemmotherapy with no indication

**TPO**

- Art. 13 Revocation and suspension
- Art. 26 Language of the labelling and medicinal product information

## 4.2 Processes after authorisation

For processes after authorisation, see Chap. “Pharmacovigilance” and Chap. “Processes following authorisation by the notification procedure of homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy with no indication ” of this guidance document.



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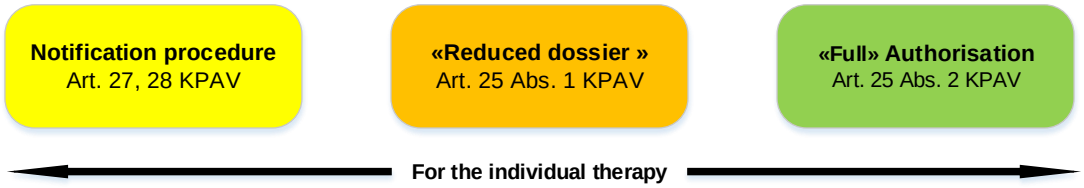
# 5 Description / General requirements / Assessment principles

## 5.1 Overview of possible authorisation procedures for products with no indication




Homeopathic and anthroposophic medicinal products with no indication and medicinal products for gemmotherapy with no indication can be authorised by various procedures, depending on the composition of the medicinal product in question and its intended use.
The decision tree in the guidance document *Authorisation of Homeopathics, anthroposophics and other complementary medicinal products HMV4* gives an overview of these procedures and helps to determine whether the notification procedure described in this guidance document can be used.

## 5.2 Formal requirements

The formal requirements are based on the guidance document *Formal requirements HMV4* and the associated Directory *Overview of documents to be submitted HMV4.*

## 5.3 Other requirements

The documentation requirements for the processes described in this guidance document for the authorisation of medicinal products by the notification procedure are described in chap. 6.

The authorisation holder must be able to demonstrate the quality of the medicinal product at any time at Swissmedic's request on the basis of documentation of the manufacture and analytical, chemical and pharmaceutical testing (Art. 25 para. 1 let. b KPTPO).

## 5.4 Pharmacovigilance

A Pharmacovigilance Plan according to Art. 11 para. 2 let. a no. 5 TPA is not required.
However, the obligation to submit PSUR (Art. 61 TPO) and the obligation to maintain a reporting system for adverse events and drug reactions (Art. 65 TPO) also apply to medicinal products authorised by the notification procedure.

## 5.5 Time limits

The time limits are based on the guidance document *Time limits for authorisation applications HMV4*.

## 5.6 Fees

The fees stated in FeeO-Swissmedic apply. Procedures that are not subject to a flat fee are charged on the basis of the work involved (Art. 4 FeeO-Swissmedic).

# 6 Authorisation by the notification procedure of homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy with no indication

## 6.1 Precondition for authorisation by the notification procedure

The preconditions set out in Art. 27 and Art. 28 KPTPO apply.
The following points in particular must be fulfilled:

- The medicinal product complies in full with the definition of a medicinal product in the corresponding school of therapy (Art. 4 para. 3 and para. 5 KPTPO).



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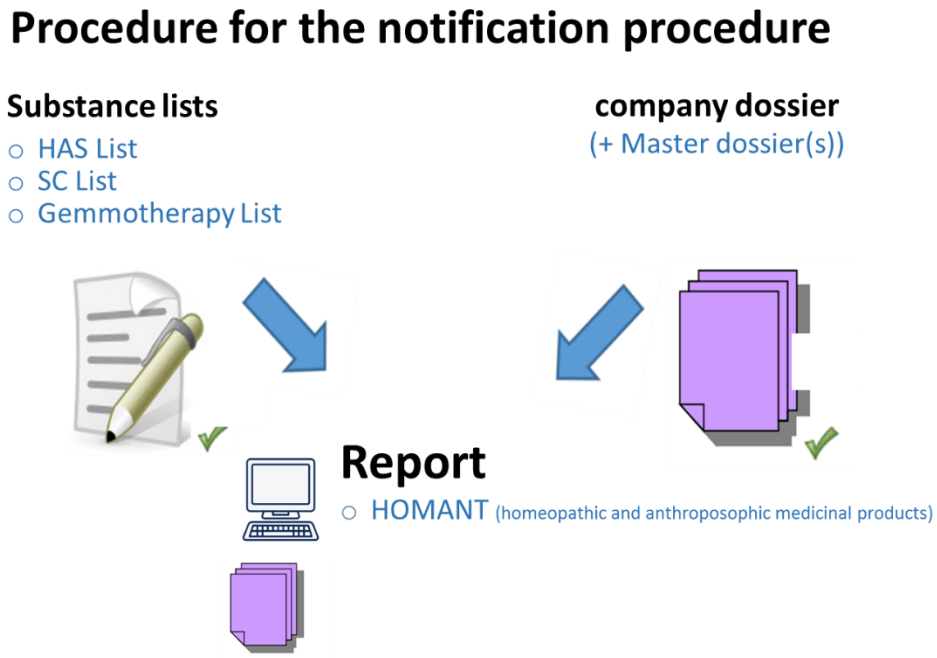
- The starting materials are exclusively substances listed in Ann. 6 KPTPO (HAS List), Ann. 7 KPTPO (SC List) or Ann. 8 KPTPO (Gemmotherapy List) (Art. 27 and Art. 28 KPTPO).
- For medicinal products of a homeopathic, spagyric or anthroposophic school of medicine, the active substances are present in the dilution or concentration stated in the column “Notification procedure from” in the HAS List or in a higher dilution (Art. 27 KPTPO).
  For medicinal products used in gemmotherapy or Schüssler therapy, the active substances are present in the dilution or concentration stated in the Gemmotherapy List or the SC List (Art. 27, Art. 28 KPTPO).
- The active substances are manufactured according to a homeopathic, anthroposophic or spagyric manufacturing procedure (Art. 20, Art. 22 and Art. 23 KPTPO).
- The excipients are monographed in the Pharmacopoeia, the HAB or the Ph. F. or in company documentation approved by Swissmedic (Art. 25 para. 1 let. a KPTPO).
- The pharmaceutical form is known in the corresponding school of medicine (Art. 23 para. 2 KPTPO).

## 6.2 Sequence of Basic notification procedure




After a basic company dossier and – where required – master dossiers have been submitted and approved, single notifications can be submitted.
Art. 41 KPTPO requires single notifications to be submitted in the form defined by Swissmedic. Swissmedic provides the HOMANT program for this purpose. This software can be downloaded from the Swissmedic website free of charge.
Only substances and potencies designated for the notification procedure in Ann. 6 KPTPO (HAS List), Ann. 7 KPTPO (SC List) or Ann. 8 KPTPO (Gemmotherapy List) can be notified. Swissmedic will subsequently examine and issue an official decision on the products notified for authorisation.

## 6.3 Basic company dossier

The formal requirements for authorisation by the notification procedure initially require the submission of the regulatory documents (Module 1) that form the basis of the electronic notification. These documents together make up the “basic company dossier”.

The basic company dossier must be compiled specifically for the manufacturer and be submitted to Swissmedic by a person or company domiciled in Switzerland with the necessary establishment licence. The authorisation holder is responsible for all authorised products in respect of health.



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Art. 38 para. 1 KPTPO defines the scope of the documentation. For the authorisation by the notification procedure of homeopathic and anthroposophic medicinal products and products for gemmotherapy with no indication, these comprise:

- Evidence that the preconditions for authorisation defined in Art. 10 para. 1 let. b and c TPA are met;
- Details of the companies involved in the manufacturing process and in monitoring, including the necessary evidence of GMP conformity. Form The *Manufacturer information HMV4* should be used for this purpose;
- Confirmation that all the preconditions for the notification procedure as defined in Art. 25 para. 1 and Art. 27 and. Art. 28 KPTPO are met;
- Confirmation that labelling is in accordance with Art. 44 KPTPO and Ann. 1a TPLRO.

If the products are manufactured in whole or in part abroad, confirmation that the medicinal products concerned are manufactured in accordance with the GMP rules valid in Switzerland (see Art. 11 para. 1 let. i MPLO) and a corresponding GMP certificate (see guidance document *GMP compliance by foreign manufacturers HMV4*) must be available for each company involved in manufacture.

If batch release is performed at various sites, separate basic company dossiers must be submitted for each site.

For medicinal products containing substances that are subject to the NarcCO and which are not diluted higher than D8/C4, evidence that the corresponding licence has been issued must be submitted to Swissmedic (Art. 38 para. 2 KPTPO).

The form *New authorisation variation in notification procedure KPTPO HMV4*provides a basis for and assistance with producing a basic company dossier and contains a checklist of the documentation and confirmations required.

All the forms, confirmations and documents required are also compiled in the guidance document *Formal requirements HMV4* and the directory of *Documents to be submitted HMV4*.

Swissmedic may request further documentation in justified cases (Art. 38, para. 2 KPTPO).

## 6.4 Master dossiers

A basic company dossier that has been approved by Swissmedic is the precondition for submitting a master dossier.

For the authorisation by the notification procedure of homeopathic and anthroposophic medicinal products with no indication, reference can be made to a master dossier approved as part of a reduced dossier (Ann. 3 no. 1.9 KPTPO).

For active substances or auxiliaries of animal or human origin and for medicinal products for parenteral use or for use on or in the eye, documentation of safety and innocuousness and of manufacture and quality must be submitted in addition to the information in the basic company dossier.

The notification procedure provides for documentation to be submitted solely in the form of master dossiers since these are generally documents that are valid for several products. If the documents apply to only one product because of the company's specific product range, the applicant should check whether authorisation with a reduced dossier would perhaps be more suitable for this medicinal product.

The following types of master dossier are possible for homeopathic and anthroposophic medicinal products (Art. 39 KPTPO):

### 6.4.1 "Substance / substance group" master dossier (Art. 39 para. 1 let. a KPTPO)

A "Substance/substance group" master dossier is required for substances of animal origin that are marked with * in the "Notification procedure from" column of the HAS List. The master dossier



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contains documents suitable for demonstrating compliance with the requirements stated in Art. 17, 18 and 19 KPTPO.

The following documents may be required in addition, depending on the animal or substance of animal origin in question:

- A risk assessment of the animal or substance of animal origin detailing the infectious agents that are likely to be encountered;
- Documentation of special measures prior to manufacture, e.g. particular breeding, husbandry, feeding, where these reduce the risk of infectious agents being present;
- Documentation of the harvesting of organ preparations;
- Documentation of inactivation stages during manufacture, e.g. sterilisation, including documentation of the validation of the corresponding manufacturing stages;
- For TSE substances the form *Substances of animal and human origin HMV4* and documents demonstrating compliance with the requirements for these substances (e.g. CEPs);
- For animals that are also used for food, evidence of compliance with the requirements for foodstuffs.

A joint master dossier can be submitted for substances from the same animal or with the same origin provided the documents therein are valid for all substances.
*Example 1: Beef in accordance with Demeter guidelines, slaughtering and organ harvesting under the same conditions, organ processing in accordance with the same regulation;*
*Example 2: Nosodes from bacterial cultures that are all bred on the same nutrient medium in accordance with the same regulation.*
There is no provision for a master dossier for human substances (nosodes of human origin) because documentation is required for each donor and each donor usually only provides the starting material for one nosode. Authorisation with a reduced dossier and the corresponding documentation is the only form of authorisation possible for products containing active substances of human origin with potencies below D24/C12.

### 6.4.2 "Substance/ substance group" master dossier for forms *Substances of animal and human origin HMV4* (Art. 39 para. 1 let. a KPTPO)

The "Substance/ substance group" master dossier for forms *Substances of animal and human origin HMV4* comprises the forms *Substances of animal and human origin HMV4* required for the single notifications and the accompanying documentation of the starting materials concerned, where these have not already been submitted in a master dossier as described in chap. ""Substance / substance group" master dossier (Art. 39 para. 1 let. a KPTPO)".

**Starting materials of animal origin**
A completed form *Substances of animal and human origin HMV4* must basically be submitted for each active substance of animal origin and for each active substance whose manufacture involved material of animal origin. The form must also take into account auxiliaries used in manufacture and feedstuffs. For substances from animals which may potentially develop TSE and thus fall within the scope of Ph. Eur. monograph 5.2.8, compliance with the requirements stated there must be documented.

**Starting materials of human origin**
A completed *Substances of animal and human origin HMV4* form (Part C) must as a rule be submitted for each active substance of human origin.

Human material falls within the scope of Ph. Eur. monograph 5.2.8. Under the notification procedure, in addition to the completed form, documents showing that TSE safety is ensured must be submitted to Swissmedic.

It is also necessary to provide confirmation that the authorisation holder has documentation demonstrating the suitability of the human donor (see Ph. Eur. monograph 1038 *Homoeopathic Preparations*; compliance with the requirements for blood donors except for the disease defined for the nosode).



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For a combination nosode containing material from several donors, the corresponding evidence must be provided for each donor.

**Auxiliaries of animal origin**
If the medicinal products to be notified contain auxiliaries of animal origin (e.g. lactose, gelatine), the form *Substances of animal and human origin HMV4* must be submitted.

**Additional/updated forms *Substances of animal and human origin HMV4***
Additional/updated forms *Substances of animal and human origin HMV4* should be submitted using a variation application for an existing "forms *Substances of animal and human origin HMV4*" master dossier.
For new single notifications, reference can only be made to forms *Substances of animal and human origin HMV4* that have already been approved as part of previous authorisations if they already exist in the form of an approved master dossier. If no corresponding master dossier exists, current versions of the forms and documentation required for the new notifications must first be submitted by the applicant as part of a master dossier.

### 6.4.3 "Pharmaceutical form" master dossier (Art. 39 para. 1 let. b KPTPO)

A "Pharmaceutical form" master dossier is required for parenterals and for medicinal products used on or in the eye. It comprises:

- Quality documents on manufacture in accordance with Ann. 3 no. 5 KPTPO;
- Documents on tolerability. Tolerability is usually independent of the active substance in single notifications using the notification procedure because of the degree to which the active substances are diluted. In other words, tolerability depends solely on the composition of the auxiliaries and the manufacturing procedure. Here tolerability can be demonstrated by means of the documents listed in Ann. 3 no. 4 KPTPO.

The required extent of the documents on tolerability depends on the degree of familiarity of the substances contained in the product. A reference to authorised products with a comparable composition, for example, can be accepted. Equally, in justified cases, e.g. sterilised solutions for injection containing adequately diluted active substances in isotonic saline solution, tolerability does not have to be demonstrated.

### 6.4.4 "Manufacturing instructions" master dossier (Art. 39 para. 1 let. c KPTPO)

Manufacturing instructions that are not described in an official pharmacopoeia but which are intended to form part of several single notifications and which comply with the requirements of Art. 4 and Art. 23 KPTPO can be submitted to Swissmedic in the form of detailed documentation for approval (Art. 23 para. 2 KPTPO). If they are approved, the submitting manufacturer can then refer to these manufacturing instructions in the notification procedure, stating the corresponding master dossier. It is recommended that the applicant contact Swissmedic before producing a master dossier of this type to discuss the requirements it must fulfil.

### 6.4.5 "Substance / substance group" master dossier for spagyric active substances (Art. 39 para. 1 let. d KPTPO)

A "Substance/substance group" master dossier is required for spagyric substances that are marked with * in the "Notification procedure from" column of the HAS List.
It must be shown in this master dossier that potentially toxic, sensitising and/or interactive ingredients and ingredients for which a maximum content is stipulated in the homeopathic monograph of the pharmacopoeia are present in the spagyric preparation in quantities no greater than in the homeopathic potency foreseen for the notification procedure.



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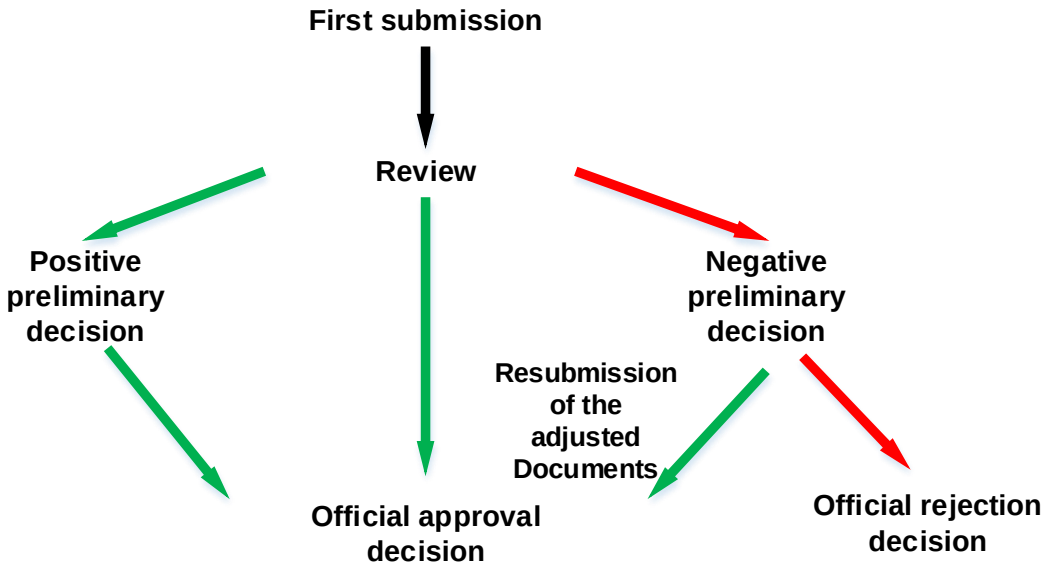
## 6.5 Single notifications

A summary description of the compilation and submission of the data for single notifications (product notifications) is given in the Annex to this guidance document; more details can be found in the *HOMANT Offline Handbook HMV4*.




Assessment of the single notifications follows the process shown in the illustration.
The single notifications are compared against the information in the basic company dossier.

If they are approved, the products are given a six-digit authorisation number which must be shown on the outer packaging of the medicinal product alongside the other information required by Ann. 1a TPLRO.

If a preliminary rejection decision is issued, the deficiencies will be listed by way of example.

### 6.5.1 Requirements for single notifications

If products containing active substances from different lists (HAS List, SC List, Gemmotherapy List) are to be notified, they must be submitted in separate applications.
Single and complex preparations containing active substances from the same list can be submitted in one application.

### 6.5.2 Specific notification requirements

In addition to the requirements for notifications listed in the *HOMANT Offline Handbook HMV4*, the following points must be observed:

- An authorisation holder may not use the same names for medicinal products from the same school of medicine (Ann. 1a TPLRO).
- The requirements stated in chap. “Information and texts on containers and packaging materials” must be taken into account when choosing the names of complex preparations.
- Single or complex preparations used in gemmotherapy may only contain active substances on the Gemmotherapy List (Ann. 8 KPTPO) in the stated potency.
- Single or complex preparations used in Schüssler therapy may only contain active substances on the SC List (Ann. 7 KPTPO) in the stated potencies.
- Complex preparations containing active substances from different schools of medicine are not permitted (with the exception of homeopathic spagyric medicinal products (Art. 4 para. 3 let. f) KPTPO).
- Only medicinal products for gemmotherapy administered by the oral route or in the pharmaceutical form “drops/spray” are eligible for the notification procedure.



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## 6.6 Information and texts on containers and packaging materials

### 6.6.1 Information

The labelling must contain the information shown in Ann. 1a TPLRO (Art. 44 para. 1 KPTPO).
As regards the labelling, the following should be noted in particular:

- only scientific names are permitted as product names (Ann. 1a para. 1 let. a TPLRO).
- no indications or dosages may be stated.
- all restrictions on use and warnings included in the HAS List (Ann. 6 KPTPO) and the Gemmotherapy List (Ann. 8 KPTPO) for the respective substances, and any other known restrictions on use and warnings, must be listed.

According to Art. 26 para. 1 TPO, the information on the packaging texts must be drafted in at least two of Switzerland's official languages.

As well as Ann. 1a nos. 2 and 3 TPLRO, the detailed information in section 6.6.3 of this guidance document should also be observed when declaring active substances.

Medicinal product information is not required. There is no need for a package leaflet provided all the necessary information can be displayed in the text on the packaging material (Art. 44 para. 2 KPTPO).

If the space available on the container/packaging material is insufficient for all the information required by Ann. 1a TPLRO, the information stated in Ann.1a no. 1 let. h and j TPLRO can be omitted from the packaging texts. In this case, the missing information should be summarised on an information leaflet to be enclosed with the product. In at least two of Switzerland's official languages. However, this information leaflet may not be designated as Patient information (PI), or use the structure given in Ann. 5.2. TPLRO, nor may this information leaflet contain information or figures that go beyond the scope of Annex 1a or that are ordered by Swissmedic.

If the composition of the preparation is repeated on an enclosed information leaflet, a translation of the active substance names commonly used in the specialist field into the national languages may be omitted.

Negative declarations (e.g. “lactose-free”) are not permitted. For excipients of particular interest according to Annex 3a TPLRO, the specified warnings should be adopted. Since a dosage is not stated for medicinal products without an indication, the information on ethanol required by Annex 3a TPLRO should be stated as a reference value per ml rather than as a dose (x mg per ml).

The labelling of medicinal products containing narcotics in dilutions up to and including D8/C4 must display the text “*Subject to the Federal Act on Narcotics and Psychotropic Substances”*. The text must be placed immediately after the name of the product.

### 6.6.2 Submission of texts on the packaging material

Packaging materials do not have to be submitted in the notification procedure.
The marketing authorisation holder is responsible for the correct design and correct content of the packaging materials.
The requirements stated in the guidance document *Packaging for human medicinal products HMV4* or Guidance document *Packaging texts for veterinary medicinal products HMV4* apply to the design of packaging materials.

### 6.6.3 Declaration

Homeopathic and anthroposophic medicines with no indication and medicinal products for gemmotherapy with no indication that have been authorised by the notification procedure are subject to the declaration requirement (Ann. 3 no. 1.3 TPLRO).

The active substances defined in Ann. 1a no. 1 para. 1 let. e TPLRO and Ann. 1a no. 1 para. 2 and 3 TPLRO should be listed. In addition to the scientific name, the name commonly used in the respective

school of therapy can optionally be stated. For anthroposophic active substances from plant-based starting materials that are not manufactured according to a homeopathic process, the requirements for herbal substances and preparations apply. In addition to the plant drugs used, the botanical name of the primary plant and the plant part used and, for extracts, the type of extract (e.g. dry extract, liquid extract), the drug-extract ratio and the extractant should be listed. Further details concerning these requirements can be found in the guidance document Authorisation of phytotherapeutic products HMV4.

Excipients should be listed in accordance with Ann. 3 and Ann. 3a TPLRO. If vehicles or excipients (e.g. ethanol, water, lactose monohydrate, glycerine) are used in the manufacture/potentisation of the active substances and account for at least 1 % of the finished product, these should be listed among the excipients. The optional mention of other excipients used during manufacture is permitted only if these have also been listed accordingly on the Full declaration form.

For medicinal products containing ingredients of animal origin as described in chapter 5.2.8 of Ph.Eur., the requirements relating to the declaration of the relevant substances stated in the guidance document Minimising the risk of TSE HMV 4 should also be observed.

For pharmaceutical forms that contain ethanol, the ethanol content in the finished product should also be stated as a percentage by volume.

For liquid pharmaceutical forms, the required figures should be stated in ml.

# 7 Processes following authorisation by the notification procedure of homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy with no indication

## 7.1 Application for variation

Variation applications may be made solely for approved basic company dossiers (Art. 38 para. 3 KPTPO) or master dossiers (Art. 39 para. 2 KPTPO). Variations are not possible for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy with no indication that have been authorised by the notification procedure (Art. 41 KPTPO).

The information in the guidance document *Variations and extensions HMV4* applies to applications for variations of a basic company dossier or a master dossier.

The preconditions for use defined in chap. “Precondition for authorisation by the notification procedure” must also be fulfilled for the requested variations.

## 7.2 Application for renewal of authorisation

It is not necessary to apply for renewal of authorisation for an approved basic company dossier or master dossier as a precondition for single notifications (Art. 37 para. 1 KPTPO).

The requirements described in the guidance document *Renewal and discontinuation of authorisation on change of status (main authorisation/export licence) HMV4* apply to applications for renewal of authorisation for single notifications.

Authorisations granted before Art. 16 para. 3 TPA entered into force must be renewed once for all medicinal products already authorised using a notification procedure (Art. 85 TPO). Once renewal of the authorisation has been granted, the authorisation is valid indefinitely.

For single notifications notified after the revised TPA of 1 January 2019 has entered into force, it is no longer necessary to apply for the authorisation to be renewed once it has been granted. The authorisation of these medicinal products is valid indefinitely (Art. 16 para. 3 TPA).

The application to renew the authorisation must be submitted with the necessary documentation at least six months before the authorisation expires (Art. 12 TPO). The requirements in the guidance document *Formal requirements HMV4* apply in addition.



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Discontinuation of the renewal of authorisation for products is an option in the context of renewal of authorisations. The information required is listed in the guidance document *Formal requirements HMV4*.

### 7.3 Notification of no marketing / interruption of distribution

The requirements listed in the guidance document *No marketing / interruption of distribution HMV4*, including the transitional provisions listed there, apply to notifications of no marketing or interruption of distribution of medicinal products authorised by the notification procedure.

Notifications according to Art. 11 TPO should be submitted for each authorised product using the form *Notification of no marketing / Interruption of distribution HMV4.*

### 7.4 Notification of discontinuation

The requirements described in the guidance document *Renewal and discontinuation of authorisation HMV4* apply to notifications of discontinuation of the authorisation of products.

Notifications of the discontinuation of master dossiers and basic company dossiers can only be submitted if notifications of the discontinuation of the authorisation for single notifications are submitted in advance or at the same time.

Discontinuation of authorised products in the context of renewal of the authorisation is described in chap. “Application for renewal of authorisation”.

## 8 HAS List, SC List, Gemmotherapy List

These lists detail the substances that are adequately known in the school of medicine concerned and the safety of which is adequately documented from the lowest potency stated for the notification procedure.

The HAS List is defined in accordance with Art. 15 para. 1 KPTPO and forms Ann. 6 of the KPTPO. The SC List is defined in accordance with Art. 15 para. 2 KPTPO and forms Ann. 7 of the KPTPO. The Gemmotherapy List is defined in accordance with Art. 27 let. b KPTPO and forms Ann. 8 of the KPTPO.



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# 9 Annex

## 9.1 Procedure for the electronic notification procedure

### 9.1.1 Submission of the basic company dossier by the authorisation holder

The process is described in chap. “Basic company dossier”. More information about the process is provided in the *HOMANT Offline Handbook HMV4*, which is also available on the Swissmedic website.

### 9.1.2 Review of the basic company dossier by Swissmedic

Swissmedic assesses the basic company dossier. Swissmedic assigns a number combination (consisting of the number assigned to the basic company dossier by Swissmedic and two further numbers) so that the products and the master dossiers can subsequently be identified as belonging to a specific authorisation holder or manufacturer, and the authorisation holder is informed of this number combination during the process of approving the basic company dossier.

### 9.1.3 Electronic registration of data by the authorisation holder

When the authorisation holder opens the HOMANT software for the first time, the number combination assigned to the basic company dossier by Swissmedic must be entered. The authorisation holder can then perform the following actions electronically with HOMANT for this basic company dossier:

- Register master dossiers (master dossier number and name)
- Register single notifications (single and complex preparations)
- Export registered data on master dossiers and single notifications for transfer to Swissmedic

Installation of the HOMANT software, the import of current substance master data and the individual stages of data entry are described in the *HOMANT Offline Handbook HMV4*.

#### 9.1.3.1 Registering master dossiers

The first step is to register the master dossiers if they are required for the subsequent registration of single notifications. HOMANT assigns a number to each master dossier in the process. A name must then be entered for the master dossier, and a brief description of the content can be added. It is important for the name of the master dossier and, where the master dossier has already been registered in HOMANT, the master dossier number generated by HOMANT to be added to the corresponding paper documents to enable Swissmedic to identify them correctly (the requirements for the labelling of master dossiers are contained in the Directory *Overview Documents to be submitted HMV4*).
This means that master dossiers can be submitted even if there are not yet any single notifications associated with them. It should be noted here that master dossiers will only be accepted if they refer to a basic company dossier that has already been approved or are submitted with an application for authorisation with a reduced dossier.
The *HOMANT Offline Handbook HMV4* contains further information on registering master dossiers.

Chap. “Master dossiers” 6.4 describes the substance groups, manufacturing procedures and pharmaceutical forms for which master dossiers are required in particular and the documentation needed.

#### 9.1.3.2 Registering single notifications

The single notifications (product data for single and complex preparations) can be registered in the second step.
Particular attention must be paid to the following points:

- If reference needs to be made to one or more master dossiers for certain starting materials, manufacturing procedures or pharmaceutical forms in a single notification, these must already be registered in HOMANT.



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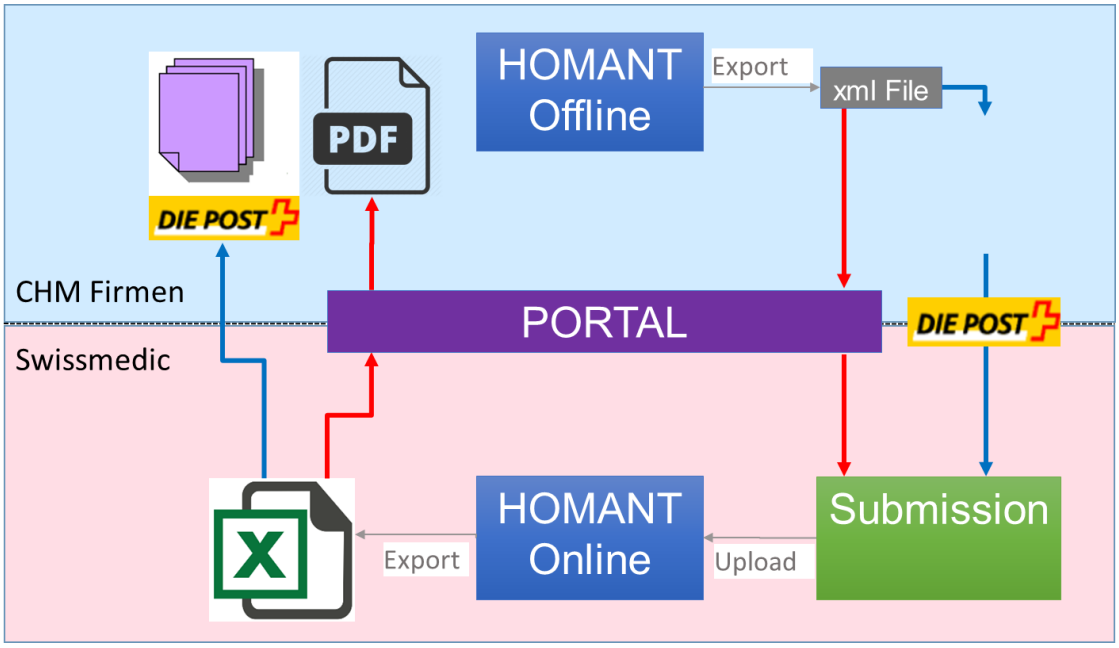
- For single preparations that have the same starting substance, the same route of administration (e.g. oral) and the same primary manufacturer, the different potencies can be listed and authorised in a single notification.
- Only one notification is necessary for complex preparations from one primary manufacturer which have the same route of administration and the same qualitative and quantitative composition. The quantities can be stated as percentages. The pharmaceutical forms to be authorised must be specified.
- In accordance with Art. 37 para. 2 KPTPO, separate single notifications are required for veterinary and human medicinal products.

The *HOMANT Offline Handbook HMV4* contains further information on registering single notifications.

### 9.1.4 Transferring single notifications to Swissmedic




Once the authorisation holder has registered all the single notifications that will be notified for authorisation in HOMANT, including any master dossiers that will be required, both can be exported together and the electronic data set (xml file) can be transferred to Swissmedic.
The *HOMANT Offline Handbook HMV4* contains further information on exporting single notifications and master dossiers.

The following two options are available for the transfer:

- Portal users can send the electronic data set to Swissmedic via the portal.
- The data set can be sent by post on a CD-ROM.

In order to avoid loss of data or errors while importing the data, each transfer of electronic data (portal or CD-ROM) must contain the form *New authorisation variation in notification procedure KPTPO HMV4* showing the information and confirmations relevant for the single notifications.

The paper documents that must be submitted for the basic company dossier and master dossiers referenced in the single notifications must be approved by Swissmedic before the electronic notifications are sent (CD-ROM).



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